



**WRIGHT**  
MEDICAL TECHNOLOGY, INC.  
5677 AIRLINE ROAD  
ARLINGTON, TN 38002  
901-867-9971

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## 510(k) Summary

Contact Person: Judy English  
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Trade Name: Sorbie Resurfacing Total Elbow System  
Common Name: Elbow Joint  
Product Classification: II  
Predicate Device: Pritchard® Elbow System (DePuy)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

### Description/Intended Use

The Sorbie Resurfacing Total Elbow System consists of humeral, ulnar, and radial head components. Each component is available in a range of sizes to fit varying anatomical requirements.

The Sorbie Resurfacing Total Elbow System is indicated for use in total elbow arthroplasty for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions: 1) noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis; 2) inflammatory degenerative joint disease including rheumatoid arthritis; 3) correction of functional deformity; 4) revision procedures where other treatments and devices have failed; and 5) treatment of fractures that are unmanageable using other techniques.

### Materials

The Sorbie Resurfacing Total Elbow System includes the following features:

- humeral and ulnar metal components manufactured from cast cobalt-chromium-molybdenum, conforming to ASTM F75;
- radial head metal components manufactured from wrought cobalt-chromium-molybdenum conforming to ASTM F1537;
- ulnar and radial head plastic components manufactured from ultra high molecular weight polyethylene conforming to ASTM F648.

### Testing Summary

Test Description	Results
Failure force analysis of the humeral component	Compressive loading will not result in failure of the component if bony support exists.
Stress analysis of the stemmed humeral component	Component exhibits peak stresses comparable to comparable to other devices and slightly over the fatigue strength of the material for joint forces typical of normal elbow joints.
Stress analysis of the ulnar component	When fully supported by bone, the component exhibits stresses well within the fatigue strength of the material.
Failure force analysis of the radial head component	All sizes demonstrate material strength properties suitable for this application.
Ulnar component lock detail testing	Any extraction forces will be countered by compressive loading placed on the components by the humerus.
Properties of the UHMWPE	The tensile properties of the test parts meet or exceed the minimum requirements by ASTM F 648.

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